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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,399	03/31/2004	Steven C. Quay	03-02CIP	5376

36814 7590 07/11/2006

NASTECH PHARMACEUTICAL COMPANY INC
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EXAMINER	
WARD, PAUL V	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/814,399	QUAY ET AL.	
	Examiner	Art Unit	
	PAUL V. WARD	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) 1 and 2 is/are allowed.

6)☒ Claim(s) 3-42 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

STATUS: The rejection of claims 3,14, 20, 31 and 37 under 35 U.S.C. 112 set forth in the Office Action date April 21, 2005 has been maintained for the reasons of record and for the reasons set forth herein.

Claim Objections

1. The objections of claims 15-42, as being misnumbered, have been overcome by Applicant's amendment.

Claim Rejections - 35 USC § 112, Second Paragraph

2. The rejections of claims 17-19 under 35 U.S.C. 112, second paragraph, have been overcome by Applicant's amendment.

Claim Rejections - 35 USC § 103

3. The rejections of claims 1-16, under 35 U.S.C. 103, have been overcome by Applicant's amendment.

Claim Rejections - 35 USC § 103

4. The rejections of claims 20-42, under 35 U.S.C. 103, have been overcome by Applicant's amendment.

Response to Arguments, regarding

Claim Rejections - 35 USC § 112, first paragraph

5. Examiner, in the Office Action dated April 21, 2005, has rejected claims 3, 14, 20, 31 and 37 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement in regards to the claimed solution having a bioavailability of at least 7% when administered intranasally.

Applicant contends that it discloses that the cyanocobalamin solutions of the invention and that when administered intranasally, it achieves bioavailability of at least 7% of the bioavailability of an intramuscular injection of cyanocobalamin. However, Applicant contentions are not persuasive.

The claims are directed to a solution that, when administered intranasally, have a bioavailability of at least 7% relative to an intramuscular injection. An adequate representation regarding the bioavailability claimed would be one that provides all of the data necessary to calculate the bioavailability claimed relative to that of an intramuscular injection.

Additionally, there are several methods of assessing bioavailability in humans and other animals. The selection of methods depends on the nature of the drug product and makes use of such parameters as time of peak plasma concentration, peak plasma concentration and the area under the plasma-time cure (AUC). However, Applicant does not provide any AUC data for bioavailability of cyanocobalamin delivered via intramuscular injection.

Further, Applicant discloses several examples in the specification to demonstrate the relative bioavailability relating to the compositions and methods claims. However, in order to demonstrate relative bioavailability, Applicant must provide four variables for the bioavailability equation. Applicant's disclosure fails to demonstrate relative bioavailability in its examples and does not disclose any AUC data for either route of administration. Thus, as a result of this finding and the lack of adequate representations in the specification, Applicant has not enabled this aspect of the

claimed composition or methods for using the same. The skilled artisan in this field would not accept the representations set forth in the instant disclosure as sufficient to enable cyanocobalamin compositions and methods of using the composition based on the bioavailability of about 7% relative to and intramuscular injection of cyanocobalamin.

Moreover, pharmacokinetic profiles are predictable and are routinely demonstrated when an applicant claims that a formulation has a specific relative bioavailability. Thus, it would be expected that the applicant could demonstrate that the formulations and methods claimed have a bioavailability of cyanocobalamin, when administered nasally, of at least 7% relative to an intramuscular injection of cyanocobalamin, and in demonstrating this, Applicant would provide the data necessary to calculate the relative bioavailability.

Thus, in order to accomplish the showing that the bioavailability of cyanocobalamin, when administered nasally, is at least 7% relative to an intramuscular injection of cyanocobalamin, the Applicant would have to show the AUC and those administered for both the intranasal and intramuscular routes to calculate the bioavailability. Therefore, the rejection of the claims under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and as set forth herein.

Conclusion

Claims 1-42 are pending. Claims 3-42 are rejected. Claims 1 and 2 are allowed.

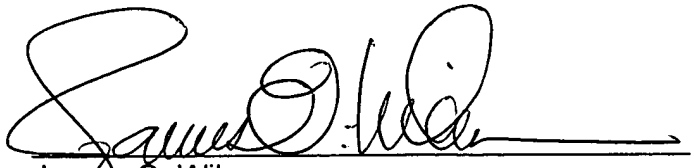
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V. WARD whose telephone number is 571-272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



James O. Wilson
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Technology Center 1600